

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MISSOURI  
CENTRAL DIVISION**

EARL RINGO, et al., )  
                          )  
Plaintiffs,           )  
                          )  
vs.                    )       **No. 09-4095-CV-C-NKC**  
                          )  
GEORGE A. LOMBARDI, et al., )  
                          )  
Defendants.           )

**Plaintiffs' Surreply Suggestions in Opposition to  
Defendants' Amended Motion to Dismiss**

Defendants' latest filing advances new arguments, but none warranting dismissal.

1. **It does not violate common sense, but reflects common sense, to require that when the Defendants use a drug to suppress pain in order to render their executions constitutional, the Defendants obey the law that applies to everyone else who administers drugs for the purpose of suppressing pain.**

Defendants distort Plaintiffs' claims in order to belittle them as "implausible" and lacking in "common sense" under *Ashcroft v. Iqbal*.<sup>1</sup> Plaintiffs are not seeking to make lethal injections "safe" in the sense that the prisoner will leave the execution chamber and go home after the procedure. Rather, Plaintiffs invoke two statutes whose core purposes include ensuring that drugs are effective for their intended use.<sup>2</sup> There is nothing "implausible" in the notion that sodium thiopental is intended to serve the medically therapeutic purpose of preventing pain during executions. That, anyway, is what this Court, the Eighth Circuit, and the Supreme Court

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<sup>1</sup>129 S. Ct. 1937 (2009); *see Reply Suggestions* (ECF Doc. 38), at 1-2.

<sup>2</sup>*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("safe and effective for its intended use"); *accord* 21 C.F.R. § 1306.04(a) (a "prescription for a controlled substance . . . must be issued for a legitimate medical purpose").

have all held.<sup>3</sup> It is undisputed that thiopental is a controlled substance. It is, therefore, entirely reasonable for federal law, in order to help ensure that the drug will serve its purpose, to require a lawful prescription and administration by a duly licensed medical professional. In the context of a lethal injection, as in any other procedure, an anesthetic is “unsafe” if it fails to accomplish its objective of rendering the person on whom it is administered unconscious or otherwise unable to feel pain.

**2. The inaction of Congress after three decades of lethal injection executions means that Congress was aware that one could make an argument that the CSA and FDCA shouldn’t apply to lethal injections, but it hasn’t amended the statute to create an exception for them.**

Similarly misguided is Defendants’ argument that Congress has known about lethal injections for decades but hasn’t expressly covered them under the Controlled Substances Act or the Food, Drug, and Cosmetics Act.<sup>4</sup> Defendants have it exactly backwards: the statutes apply here because Congress hasn’t exempted lethal injection. The CSA and the FDCA are statutes of general application relating to “controlled substances” and “drugs.” Defendants do not even dispute that their conduct falls within the literal meaning of these terms. Congress has created a host of exceptions to these statutory terms, but none for lethal injections.<sup>5</sup> Likewise, the FDA may, by formally promulgating a regulation, exempt any “drug” from FDCA approval requirements when “such requirements are not necessary for the protection of the public health.”<sup>6</sup> There is no such exemption for lethal injection drugs. Neither are Defendants aided by the

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<sup>3</sup>*Baze v. Rees*, 128 S. Ct. 1520, 1533 (2008); *Taylor v. Crawford*, 487 F.3d 1072, 1083-84 (8th Cir. 2007); *Clemons v. Crawford*, Case No. 07-4129-CV-C-FJG, ECF Doc. 89, at 3.

<sup>4</sup>ECF Doc.38, at 2-3.

<sup>5</sup>See Suggestions in Opposition to Motion to Dismiss (ECF Doc. 37), at 24-25.

<sup>6</sup>21 U.S.C. § 353(b)(3).

absence of any prosecutions against executioners. A law does not cease to be a law by non-enforcement.<sup>7</sup>

**3. Applying the CSA and FDCA to lethal injections does not require or involve preemption of Missouri law.**

Defendants next argue that if they must obtain a prescription to use thiopental in lethal injections, then Plaintiffs will have to demonstrate that federal law “preempts” Missouri law and in effect prohibits lethal injection.<sup>8</sup> But nothing compels Defendants to violate the law by failing to obtain a prescription for a controlled substance. That requirement does not “conflict” with state law; it is not impeded by any substantial “obstacle” in state law; it plainly does not forbid lethal injection in general or by a three-drug sequence in particular.<sup>9</sup> Yet Defendants apparently refuse to even *seek* a prescription. Defendants would prefer not to comply with federal law, but that is not the type of “sufficient obstacle” which creates preemption.

In their reply, Defendants refer to themselves as “the State.” It is not “the State” that is violating these federal statutes; its method-of-execution statute does not mandate or encourage the violation of either the CSA or the FDCA. Individual, unlawful choices are at issue in this action. One need not invoke the rubric of preemption to postulate that Defendants, no less than the President himself, are “subject to the same laws that apply to all other members of our society.”<sup>10</sup>

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<sup>7</sup>*United States v. Elliott*, 266 F. Supp. 318, 325-26 (S.D.N.Y. 1967) (non-enforcement for fifty years); *United States v. Morrison*, 596 F. Supp. 2d 661, 702 (E.D.N.Y. 2009) (noting universal rejection of the doctrine of desuetude, outside of West Virginia).

<sup>8</sup>ECF Doc. 38, at 4-6.

<sup>9</sup>*English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990) (criteria for preemption).

<sup>10</sup>*Jones v. Clinton*, 72 F.3d 1354, 1358 (8th Cir. 1996), *aff’d sub. nom. Clinton v. Jones*, 520 U.S. 681 (1997).

**4. In seeking to interject principles of preemption into the case, Defendants rely on factual propositions that are both beyond the pleadings and disprovable.**

Defendants argue that Plaintiffs must prove that some sedative other than thiopental is suitable for lethal injections.<sup>11</sup> Defendants baldly state that any such “substitute chemicals” are necessarily “also controlled substances that the State would have to obtain a prescription to use.”<sup>12</sup> But that premise is hardly self-proving and cannot be established from the pleadings. It is well-established that a court cannot consider matters beyond the pleadings without converting the motion into a motion for summary judgment—and affording the accompanying protections, including discovery, to the non-moving party.<sup>13</sup> As with their assertion of *res judicata*, Defendants are essentially moving for summary judgment. It is too early for them to do so.

Furthermore, even if Defendants’ argument about “substitute chemicals” weren’t premature, it is refuted by information readily available to the parties and the Court. Counsel’s preliminary research reveals an abundance of sedatives that are not controlled substances—or that are Class V controlled substances which do not require a prescription—any of which will induce unconsciousness in sufficient amounts or in combination.<sup>14</sup> These include soma or carisoprodol,<sup>15</sup> pregabalin,<sup>16</sup> codeine and various opiates,<sup>17</sup> as well as the common, over-the-

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<sup>11</sup>ECF Doc. 38, at 4-5.

<sup>12</sup>*Id.* at 4.

<sup>13</sup>Fed. R. Civ. P. 12(d); *Gibb v. Scott*, 958 F.2d 814, 816-17 (8th Cir. 1992).

<sup>14</sup>21 U.S.C. § 829 (contrasting Class V substances with Classes III and IV).

<sup>15</sup>*United States v. Armstrong*, 550 F.3d 382, 405 n.39 (5th Cir. 2008).

<sup>16</sup>21 C.F.R. § 1308.15; *see also* <<<http://en.wikipedia.org/wiki/Pregabalin>>> (last visited Sept. 27, 2009).

<sup>17</sup>*See* 21 C.F.R. § 1308.15, listing concentrations at which these drugs are Schedule V substances, which, presumably, may be administered sequentially or in combination with other sedatives without violating the Schedule V restrictions.

counter antihistamine diphenhydramine (a/k/a Benadryl).<sup>18</sup> By citing these obvious facts, Plaintiffs in no way waive the right to proceed with discovery, and are simply answering the argument that their claims are “implausible” as a matter of law. Nothing Plaintiffs have uncovered in evaluating Defendants’ assertions were, however, covert or available only to them rather than equally available to Defendants.

Of course, a more timely example of a powerful sedative is propofol—the anesthetic that killed Michael Jackson, and which is not a controlled substance.<sup>19</sup> Propofol has overtaken sodium thiopental as the agent of choice among anesthesiologists because it lacks side effects and leaves the body quickly.<sup>20</sup> But if not carefully monitored, the “milk of amnesia” slows breathing and reduces blood pressure to the point of death.<sup>21</sup> In Jackson’s case, the doctor who allegedly obtained and injected the propofol was not licensed to prescribe or dispense controlled substances in California, even though he could in two other states. He could legally, however, administer propofol to Jackson because it is not a controlled substance.<sup>22</sup>

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<sup>18</sup>See Juan Santiago-Palma et al, “Diphenhydramine as an Analgesic Adjuvant in Refractory Cancer Pain,” *Journal of Pain and Symptom Management*, Vol. 22: 2 (Aug. 2001) (Abstract available at <<http://patient-research.elsevier.com/patientresearch/displayAbs?key=S0885392401003116>>>).

<sup>19</sup>See Pam Belluck, “High-Risk Drug Is in Spotlight After High-Profile Death,” *New York Times*, Aug. 7, 2009; see also <[http://www.deadiversion.usdoj.gov/schedules/orangebook/e\\_cs\\_sched.pdf](http://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf)>> (last visited Sept. 27, 2009) (list of all controlled substances).

<sup>20</sup>Belluck, *supra*.

<sup>21</sup>*Id.*

<sup>22</sup>Jana Winter, “Michael Jackson’s Doctor Not Licensed to Prescribe Controlled Drugs in California,” July 6, 2009, available at <<http://www.foxnews.com/story/0,2933,530242,00.html>>> (last visited Sept. 27, 2009); “Michael Jackson’s Doctor Not Licensed to Prescribe Even Some Cough Syrups,” July 6, 2009, available at <[http://www.huffingtonpost.com/2009/07/06/michael-jacksons-doctor-n\\_n\\_226545.html](http://www.huffingtonpost.com/2009/07/06/michael-jacksons-doctor-n_n_226545.html)>> (last visited Sept. 27, 2009).

Recent events, then, offer two relevant lessons. First, they show that not every powerful sedative is a controlled substance as Defendants assert. Second and more importantly, the events suggest that individuals who are not duly licensed to administer potent drugs cannot be relied on to select or administer them competently—or, as Defendants would say, “safely.” Compliance with federal law effectively limits that danger, as a matter of common sense.

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 28th day of September, 2009, to Andrew W. Hassell, Michael J. Spillane and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

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